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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,604	06/03/2005	Esa T Jarvi	1593 WO/US	3551
24289	7590	10/19/2007		
Mallinckrodt Inc. 675 McDonnell Boulevard HAZELWOOD, MO 63042			EXAMINER RAHMANI, NILOOFAR	
			ART UNIT	PAPER NUMBER
			1625	
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			10/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,604	Applicant(s) JARVI ET AL.	
	Examiner Niloofer Rahmani	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,7,11,14,17,27,30,35-37,41,42,44,47 and 50-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,7,11,14,17,27,30,35-37,41,42,44,47 and 50-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 6-7, 11, 14, 17, 27, 30, 35-37, 41-42, 44, 47, 50-53 are currently pending in the instant application. Claims 2-5, 8-10, 12-13, 15-16, 18-26, 28-29, 31-34, 38-40, 43, 45-46, 48-49 are cancelled.

2. **Priority**

This application was filed on 06/03/2005, which is a 371 of PCT/US03/39951, filed on 12/16/2003, which claims benefit of 60/435,763, filed on 12/18/2002.

3. **Claim Rejections - Obvious Double Patenting**

Claims 1, 6-7, 11, 14, 17, 27, 30, 35-37, 41-42, 44, 47, 50-53 are provisionally rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over the claims 1-72 of Jarvi et al. application No. 10/594,486. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention embraces the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Jarvi et al. claimed identical process in claims 1-72 as the instant claims 1, 6-7, 11, 14, 17, 27, 30, 35-37, 41-42, 44, 47, 50-53.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the issued claims is the claims are not word for word identical but the scope of both sets of claims overlaps mostly significantly with each other.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

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The issued claims 1-72 are therefore fully embraced by the instant claims 1, 6-7, 11, 14, 17, 27, 30, 35-37, 41-42, 44, 47, 50-53 of the application # 10/594,486.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 168 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1,6-7, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by George et al. US 4,847,263. George et al. disclosed the instant

claimed process on the columns 7-10, and columns 2-3, Example 1(1.3 and 1.4), wherein the compound of formula (VII) in the presence of SOCl_2 and Rongalite converted to the compound of Formula (VIII). Therefore, the instant claims are anticipated by George et al.

5. Claims 1,6-7, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by George et al. US 4,808,594. George et al. disclosed the instant claimed process on the columns 1 and 5-6, wherein the compound of formula (VI) is converted to the compound of formula (I), and columns 3-4, Example 1(4.), wherein the compound of formula (VI) in the presence of SOCl_2 , CH_2Cl_2 and Rongalite converted to the compound of Formula (I). Therefore, the instant claims are anticipated by George et al.

6. Claims 1,6-7, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Schloemer et al. US 6,861,525. Schloemer et al. disclosed the instant claimed process on the columns 5-6, wherein the compound of formula (III) is converted to the compound of formula (I), and columns 3-4, the process is in the presence of phosphorus tribromide and organic solvents such as THF, 1,2-dichloroethane, methylisobutyl ketone. Therefore, the instant claims are anticipated by Schloemer et al.

7. ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14, 17, 27, 30, 35-37, 41-42, 44, 47, 50-53 are rejected under 103(a) as being unpatentable over George et al. US 4,847,263.

Determination of the scope and content of the prior art (MPEP §2141.01)

George et al. disclosed the instant claimed process on the columns 7-10, and columns 2-3, Example 1(1.3 and 1.4), wherein the compound of formula (VII) in the presence of SOCl_2 and Rongalite converted to the compound of Formula (VIII).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art process is that the instant claims include specific acid, catalyst, or halide.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the process of George et al. to obtain the instant process. Because changing one acid to another or one catalyst to another or one halide to another is within of the ordinary skill in the art.

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8. Claims 14, 17, 27, 30, 35-37, 41-42, 44, 47, 50-53 are rejected under 103(a) as being unpatentable over George et al. US 4,808,594.

Determination of the scope and content of the prior art (MPEP §2141.01)

George et al. disclosed the instant claimed process on the columns 1 and 5-6, wherein the compound of formula (VI) is converted to the compound of formula (I), and columns 3-4, Example 1(4.), wherein the compound of formula (VI) in the presence of SOCl_2 , CH_2Cl_2 and Rongalite converted to the compound of Formula (I).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art process is that the instant claims include specific acid, catalyst, or halide.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the process of George et al. to obtain the instant process. Because changing one acid to another or one catalyst to another or one halide to another is within of the ordinary skill in the art.

9. Claims 14, 17, 27, 30, 35-37, 41-42, 44, 47, 50-53 are rejected under 103(a) as being unpatentable over Schloemer et al. US 6,861,525.

Determination of the scope and content of the prior art (MPEP §2141.01)

Schloemer et al. disclosed the instant claimed process on the columns 5-6, wherein the compound of formula (III) is converted to the compound of formula (I), and columns 3-4, the process is in the presence of phosphorus tribromide

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and organic solvents such as THF, 1,2-dichloroethane, methylisobutyl ketone.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art process is that the instant claims include specific acid, catalyst, or halide.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the process of Schloemer et al. to obtain the instant process. Because changing one acid to another or one catalyst to another or one halide to another is within of the ordinary skill in the art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

10/16/2007

NR



D. MARGARET SEAMAN

PRIMARY EXAMINER

GROUP 1625